

Nuclear Regulatory Commission

§ 32.71

(4) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.103; and

(5) Quality control procedures have been established to satisfy the requirements of § 32.62.

[30 FR 9905, Aug. 10, 1965, as amended at 43 FR 6923, Feb. 17, 1978; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§ 32.62 Same: Quality assurance; prohibition of transfer.

(a) Each person licensed under § 32.61 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(b) Each person licensed under § 32.61 shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(c) Each person licensed under § 32.61 shall take a random sample of the size required by the table in § 32.110 for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(1) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks, as evidenced by physical contact between the water and the strontium-90, shall be considered as a defective unit.

(2) The immersion test water from the preceding test in paragraph (c)(1) of this section shall be measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of

the original amount of strontium-90 in any device, the device shall be considered as a defective unit.

(d) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (c) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that:

(1) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of strontium-90 in any 24-hour period; and

(2) The operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(e) No person licensed under § 32.61 shall transfer to persons generally licensed under § 31.10 of this chapter:

(1) Any device which has been tested and found defective under the criteria and procedures specified in this § 32.62 unless the defective units have been repaired or reworked and then met the tests set out in paragraph (c) of this section; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (d) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (c) of this section.

[30 FR 9905, Aug. 10, 1965, as amended at 39 FR 22130, June 20, 1974; 39 FR 26397, July 19, 1974; 43 FR 6923, Feb. 17, 1978]

§ 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.

An application for a specific license to manufacturer or distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter.